

BAKER BOTTS LLP

700 K STREET, N.W.
WASHINGTON, D.C.
20001

TEL +1 202.639.7700
FAX +1 202.639.7890
BakerBotts.com

AUSTIN
BRUSSELS
DALLAS
DUBAI
HOUSTON
LONDON

NEW YORK
PALO ALTO
RIYADH
SAN FRANCISCO
WASHINGTON

May 19, 2022

Andrew George
TEL: 2026397764
FAX: 2025854084
andrew.george@bakerbotts.com

The Honorable Deborah L. Boardman
United States District Judge
U.S. District Court for the District of Maryland
101 West Lombard Street
Baltimore, MD 21201

Re: Lacks v. Thermo Fisher Scientific, Inc., No. 1:21-cv-02524

Dear Judge Boardman:

We write to provide the Court with information responsive to questions raised during the May 17, 2022 hearing regarding when Thermo Fisher was conferred the alleged benefit—the HeLa cell line. Am. Compl. ¶¶ 48-52. As shown by the materials included below—patent filings subject to judicial notice and subject to the public records exception to the rule against hearsay—there is no reasonable question that Thermo Fisher was conferred the HeLa cell line long before the limitations period.

The below list of patents assigned to Thermo Fisher or Invitrogen¹ demonstrates the use (and thus possession) of the HeLa cell line in experiments by Thermo Fisher or Invitrogen before October 4, 2018. Each of these patents was publicly available, per U.S. Patent and Trademark Office practice, by the earlier of the identified publication date or issuance date.² See 35 U.S.C § 122(b). (Emphases added in each reference below).

1. U.S. Patent No. 6,017,754, at Col. 3, Lns. 40-42 (filed Aug. 24, 1995) (issued Jan. 25, 2000) (assigned to Invitrogen) (“FIG. 3B demonstrates transfected ‘293’ (ATCC #CRL-1573) and **HeLa cells** (ATCC #CCL-2) **transfected with pPhOx.**”).³

¹ As explained in our underlying Motion, Invitrogen—noted in the 2010 publication of *The Immortal Life of Henrietta Lacks* as “today . . . sell[ing] HeLa products”—was acquired by Thermo Fisher in 2014. Mot. 5-6 n.9.

² Copies of these patents are attached as Attachment A. They are a sampling of patents assigned to Thermo Fisher or Invitrogen that specifically reference the HeLa cell line; we have not included all such patents to avoid overwhelming the Court. Neither Thermo Fisher nor its subsidiaries patent HeLa cells themselves. Rather, these patents describe testing the claimed inventions—such as “an siRNA molecule” or “cationic compound”—with HeLa cells to determine whether the invention works.

³ The age of this patent—publicly issued 22 years ago—illustrates the potential difficulty of determining the first date of conferral after the length of delay in this case. Moreover, because many of these publicly available patent

BAKER BOTTS LLP

The Honorable Deborah L. Boardman

- 2 -

May 19, 2022

2. U.S. Patent No. 7,432,372 B2, at Col. 62, Lns. 26-27 (filed Nov. 1, 2004) (published May 5, 2005) (issued Oct. 7, 2008) (assigned to Invitrogen) (“**HeLa and HepG2 cells are obtained from the American Type Culture Collection.**”).⁴
3. U.S. Patent No. 7,479,573 B2, at Col. 9, Lns. 51-52 (filed Jan. 21, 2005) (published July 28, 2005) (issued Jan. 20, 2009) (assigned to Invitrogen) (“FIG. 4 is a graph showing **transfection of HeLa cells** with cationic transfection reagents.”).
4. U.S. Patent No. 8,932,850 B2, at Col. 12, Lns. 58-60 (filed June 13, 2005) (published Nov. 29, 2007) (issued Jan. 13, 2015) (assigned to Invitrogen) (“**HeLa cell line (ATCC, CCL-2) and SK-OV-3 cell line (ATCC, HTB-77) were employed for experiments**”).
5. U.S. Patent No. 8,937,172, at Col. 30, Lns. 11-12 (filed Feb. 12, 2013) (published Aug. 14, 2014) (issued Jan. 20, 2015) (assigned to Thermo Fisher) (“**HeLa (ATCC, CCL-2, cervical epithelial adenocarcinoma)**”).
6. U.S. Patent No. 9,150,862 B2, at Col. 25, Lns. 40-48 (filed Aug. 27, 2013) (published Jan. 30, 2014) (issued Oct. 6, 2015) (assigned to Thermo Fisher) (“**transfected into HeLa cells (ATCC, #CCL-2)**”).
7. U.S. Patent No. 8,907,077, at Col. 51, Lns. 49-50 (filed Dec. 6, 2013) (published Apr. 3, 2014) (issued Dec. 9, 2014) (assigned to Thermo Fisher) (“**HeLa cells were grown in Dulbecco’s modified Eagle’s medium (DMEM)**”).

The Court is permitted to take judicial notice of these patents under Federal Rule of Evidence 201. Rule 201(c)(2) requires notice be taken where requested and where the Court is supplied with the necessary information. Rule 201(b)(2) permits the Court to judicially notice facts not subject to reasonable dispute where they can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.

It is “well-established that a court may take judicial notice of patents or patent applications.” *Anderson v. Kimberly-Clark Corp.*, 570 F. App’x 927, 931, 932 n.3, 932 n.4 (Fed. Cir. 2014) (noting that the district court could properly take notice of a patent application to assess invalidity at the motion for judgment on the pleadings stage (which employs “the same test as a motion under Rule 12(b)(6)”) (citing *Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 954 n.27 (Fed. Cir. 1993))). Furthermore, patents and patent applications are not barred from consideration by the hearsay rule because they are admissible as public records and may be considered for their truth under Federal Rule of Evidence 803(8). *Valve Corp. v. Ironburg Inventions Ltd.*, 8 F.4th 1364, 1370 n.6 (Fed. Cir. 2021) (finding that a patent and related filings were subject to judicial

documents show a conferral of the HeLa cell line before the 2010 publication of *The Immortal Life of Henrietta Lacks* and show a third-party supplier—American Type Culture Collection (“ATCC”)—as the source, Plaintiff cannot replead facts to establish Thermo Fisher was not a bona fide purchaser of the HeLa cell line.

⁴ It is standard convention for scientists to reference the sources of materials in describing experiments so that others may duplicate their efforts to verify the results. The reference to ATCC as the source of the HeLa cells in many of the listed patents is to the American Type Culture Collection, a non-profit organization that today sells HeLa cells, including to companies like Thermo Fisher, for \$520.00. HeLa, <https://www.atcc.org/products/ccl-2> (last visited May 19, 2022).

BAKER BOTTS LLP

The Honorable Deborah L. Boardman

- 3 -

May 19, 2022

notice and could be considered for their truth as public records under Rule 803(8)); *Kaempe v. Myers*, 367 F.3d 958, 965 (D.C. Cir. 2004) (documents recorded by the Patent and Trademark office “are public records subject to judicial notice on a motion to dismiss”). Thus, the Court may take notice of the above patents to eliminate any possible doubt that Plaintiff’s claim accrued before October 4, 2018.

This Court has taken judicial notice of facts in public records to establish the limitations period for a claim while considering a Rule 12(b)(6) motion to dismiss. *See, e.g., Dale v. Mayor*, No. CIV. WDG-14-2152, 2015 WL 5521815, at *5 (D. Md. Sept. 15, 2015) (taking judicial notice of state court records to establish the limitations period for false arrest and other analogous § 1983 claims and dismissing them as untimely because the complaint was filed outside Maryland’s 3-year statute of limitations) (citing *Philips v. Pitt Cnty. Mem’l Hosp.*, 572 F.3d 176, 180 (4th Cir. 2009) (“In reviewing a Rule 12(b)(6) dismissal, we may properly take judicial notice of matters of public record.”)). All patent filings are submitted under penalty of perjury at the time of filing, and, upon issuance, are presumed valid. 35 U.S.C. § 115(a), (b), and (i) (verification requirement); 35 U.S.C. § 282 (presumption of validity). They are, moreover, corroborated by non-Thermo Fisher patents and patent applications listed below (emphases added). All predate the limitations period and show Thermo Fisher or Invitrogen as the source of products named in the Complaint (at Paragraph 39)—indicating that Thermo Fisher or Invitrogen possessed the products prior to the reference patent application filing dates. (Emphases added.)

1. U.S. Patent No. 8,198,077 B2, at Col. 9, Lns. 45-47 (filed Jan. 15, 2004) (published Sept. 21, 2006) (issued June 12, 2012) (“**In this study, we used ‘T-Rex’ HeLa cells (Invitrogen)** that constitutively express the tetR protein.”).
2. U.S. Patent App. Pub. No. 2007/0122798 A1, at ¶ [0035] (filed Mar. 3, 2004) (published May 31, 2007) (“**The Hela T-Rex cells (Invitrogen ref: R714-07)**, which express the TetR repressor, were then transduced ...”).
3. U.S. Patent No. 7,683,036 B2, at Col. 198, Lns. 35-40 (filed July 30, 2004) (published Nov. 24, 2005) (issued March 23, 2010) (“**The T-REx™-HeLa cell line (Invitrogen Corp., Carlsbad, Calif.)** was used for either stable or transient transfections with plasmids constitutively expressing miRNAs, pre-miRNAs, pri-miRNAs or mimics thereof, and, in some cases, antisense oligomeric compounds targeting the expressed miRNA were also transfected into the cells.”).
4. US Patent No. 7,759,318 B1, at Col. 81, Lns. 54-67 (filed May 27, 2005) (issued July 20, 2010) (“In one embodiment, **the T-REx™-HeLa cell line (Invitrogen Corp., Carlsbad, Calif.)** can be used for transient transfections with plasmids constitutively expressing microRNAs and, in some cases, antisense oligomeric compounds targeting the expressed microRNA are also transfected into the cells. It is understood that other mammalian cells lines can also be used in this reporter system.”).
5. U.S. Patent App. Pub. No. 2008/0312298 A1, at ¶ [0451] (filed Apr. 11, 2008) (published December 18, 2008) (“The expression plasmid containing the gene for Flag-PrX is

BAKER BOTTS LLP

The Honorable Deborah L. Boardman

- 4 -

May 19, 2022

- transfected into a Tet system-compatible cell lines (such as HEK293 T-Rex or **HeLa T-Rex from Invitrogen**) and clones are selected ...”).
6. US Patent App. Pub. No. 2011/0293593 A1, at ¶ [0120] (filed Feb.11, 2009) (published Dec. 1, 2011) (“All adherent cells--HEK-293T, EcR-293 (Invitrogen), HeLa, **HeLa T-Rex (Invitrogen)**, and HepG2--were cultured in Dulbecco's modified Eagle's medium.”).
 7. U.S. Patent No. 9,796,967 B2, Col. 54, Ln. 52 – Col. 55, Ln. 13 (filed Aug. 1, 2013) (published July 16, 2015) (“Expression of the protein of interest can be made possible with a mammalian cell-free extract **similar to the product currently commercialized by Thermo Scientific based on HeLa cell extracts. The Thermo Scientific 1-Step Human High-Yield In Vitro Translation (IVT)** is a cell-free protein expression system that provides all of the essential components required for transcription and translation. The kits are optimized with Accessory Proteins and Reaction Mixes that support protein synthesis for up to 24 hours using a DNA template. The 1-Step Human High-Yield IVT Kits, with a continuous-feed device, enable the expression of functional proteins. The current system uses modified HeLa cell extracts to take advantage of the robust human translation machinery and generate functional full length proteins.”).
 8. U.S. Patent App. Pub. No. 2017/0029823 A1, at ¶ [0107] (filed Jul. 28, 2016) (published Feb. 2, 2017) (“Exemplary mammalian cell lines include: ... **T-REx™-HeLa cell line**...”).
 9. U.S. Patent No. US 10,266,866 B2, at Col. 10, Ln. 6-15 (filed Nov. 23, 2016) (published June 1, 2017) (issued April 23, 2019) (“[A]pomyoglobin and **HeLa digest were purchased from Thermo Fisher** (San Jose, Calif.”).⁵

The citations in these public documents (the reference patents) leave no reasonable question as to the fact that Thermo Fisher was conferred the HeLa cell line long before the limitations period in this case. Thus, Plaintiff’s claim is time-barred, and further proceedings or amendment would be futile.

Sincerely,



Andrew George

Tonya Kelly Cronin (Bar No. 27166)
BAKER DONELSON
100 Light St.
Baltimore, MD 21202
Tel.:410-862-1049
tykelly@bakerdonelson.com

⁵ Copies of these patents and applications are attached as Attachment B.

BAKER BOTTS_{LLP}

The Honorable Deborah L. Boardman

- 5 -

May 19, 2022

Nadira Clarke (Fed. Bar No. 20254)
Andrew T. George (Fed. Bar No. 19755)
Adam Dec (Fed. Bar No. 22038)
Eileen F. Hyde*
JoAnna B. Adkisson*
BAKER BOTTS L.L.P.
700 K St. NW
Washington, DC 20001
Tel.: 202-639-7764
nadira.clarke@bakerbotts.com
andrew.george@bakerbotts.com
adam.dec@bakerbotts.com
eileen.hyde@bakerbotts.com
joanna.adkisson@bakerbotts.com

**Admitted pro hac vice*

Attorneys for Defendant

Attachments